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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,208

05/10/2001

Jian Chen

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09/20/2002

GENENTECH, INC.

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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,208

Applicant(s)

CHEN ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66 is/are allowed.
- 6) ☒ Claim(s) 60, 63, 69 and 70 is/are rejected.
- 7) ☒ Claim(s) 61, 62, 64, 65, 67 and 68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 9, 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

Applicant's election without traverse of Group II invention, directed to SEQ ID NO:3, in Paper No. 12, filed on 12 August 2002 is acknowledged. Applicant's amendment in paper No. 12 is acknowledged and entered. Following the amendment, the original claims 43-59 are canceled, and the new claims 60-70 are added.

Currently, claims 60-70 are pending and under consideration.

The references listed on the PTO-1449 in paper No. 10 are not present in the current application file. However, as the reference copies provided in the related case, US application 09/854,280, listed the PTO-1449 in paper No. 7, are identical to those listed on the PTO-1449 in paper No. 10 of the instant application, they are considered in the present Office Action.

Formal Matters:

Priority

This application claims priority to US provisional applications 60/085,579 and 60/113,621, and US application 09/311,832. For the following reasons, the Examiner finds that the present claims 60-70 are not supported by all priority applications.

US provisional application 60/085,579 filed on 15 May 1998 does not disclose SEQ ID NO:3 and 4 as claimed in the instant application. US provisional application 60/113,621, filed on 23 December 1998 merely discloses the sequences of the present SEQ ID NO:3 and 4, and provides no specific, substantial and credible utility thereof, therefore, it does not support the present invention in the manner required by 35 U.S.C. 101 and 112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filing date of the two claimed US provisional applications.

Claims

Claim 65 is objected to for depending upon a canceled claim, claim 48.

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Claims 67 and 68 are objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are dependent from claim 60, which is drawn to an isolated polypeptide. The additional limitations in claims 67 and 68 are directed to “a composition”, which is not further limiting the polypeptide in the independent claim. Accordingly, claims 67 and 68, the dependent claims of claim 60, do not further limit claim 60.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60, 63, 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to the polypeptide of SEQ ID NO:3, or the polypeptide encoded by the cDNA of ATCC 203552, does not reasonably provide enablement for all polypeptide “having at least 80% amino acid sequence identity to” above sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 60, 63, 69 and 70 are directed to variant polypeptides having at least 80% sequence identity to the amino acid sequence of SEQ ID NO:3 (as claim 60, for example), or to the amino acid sequence encoded by the cDNA of ATCC 203552 (as claim 63), which read on any or all variants meeting the sequence limitation, and encoding polypeptides either with or without functional activity. However, while the specification teaches that IL-17C

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(PRO1122) of SEQ ID NO:3 induces production of TNF- α (Example 10), it provides no guidance as to how the skilled artisan could use an inactive polypeptide variant of SEQ ID NO:3, as no functional limitation associated with the variants in the claims. Therefore, it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to use the variants encoding polypeptides that are inactive for any purpose stated in the specification.

Due to the lack of direction/guidance presented in the specification regarding to how to use the inactive variants of SEQ ID NO:3, the absence of working examples directed to same, and working examples directed to the active variants or fragments of SEQ ID NO:3, the nature of the invention which is drawn to a polypeptide supposed to be useful in research and clinical applications, the lack of predictability, and the breadth of the claims which embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ruben et al. (WO9961617-A1, provided by applicants) discloses a human IL-21 protein (Figure 6A-B), which amino acid sequence is 100% identical to SEQ ID NO:3 of the present invention (see appended computer printout of sequence search results).

Conclusion:

Claim 66 is allowable.

Claims 61, 62, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 65 is objected to as being dependent upon a canceled claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

**LORRAINE SPECTOR
PRIMARY EXAMINER**

DJ
9/16/02